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510(k) SUMMARY
SIEMENS AG
T1 CONTROL HIGH-SPEED DENTAL HANDPIECE

1. DATE PREPARED

December 30, 1996

2. SUBMITTER

Siemens AG
Medical Technology
Dental Systems
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3. CONTACT

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4. DEVICE NAME

Proprietary Name:	T1 CONTROL High Speed Dental Handpiece
Common/Usual Name:	Dental Handpiece
Classification Name:	Air-powered Dental Handpiece

5. DEVICE CLASSIFICATION

Air-powered dental handpieces and accessories have been classified under Section 513 of the Act as Class I devices by the Dental Devices Panel.

Classification Regulation: 21 CFR 872.4200

Product Code: 76 EFB

6. DEVICE DESCRIPTION AND COMPARISON TO PREDICATE PRODUCTS

The Siemens T1 CONTROL high speed dental handpiece is intended for use in the dental operatory to prepare dental cavities for restorations, such as fillings. The device is an air-powered, high speed handpiece constructed of titanium. The device is reusable, is ergonomically shaped, and includes a solid fibre optic rod built-in light system. The water delivery geometry includes three spray nozzles in the device head with one-way retraction valves to prevent the ingress of external air or liquid when the spray system is shut down. The device can be sterilized by the steam autoclave method.

The Siemens T1 CONTROL high-speed dental handpiece is similar in design, function, and intended use to other high-speed dental handpieces currently in U.S. commercial distribution. Examples of substantially equivalent devices include the Tradition high-speed handpiece manufactured by Midwest (K863677), the Star Dental 430 series high-speed handpiece manufactured by DEN-TAL-EZ, Inc. (K960719), and the W&H 898 Top Light high-speed handpiece manufactured by A-DEC, Inc. (K944710).

7. PERFORMANCE TESTING

The Siemens T1 CONTROL Dental Handpiece complies with ISO Standard 7785-1 for High Speed Air Turbine Handpieces, ISO Standard 1797 for Dental Rotary Instruments - Shanks, and ISO Standard 9168 for Dental Handpieces - Hose Connectors. Additional performance testing was conducted on the device to validate the sterilization process and device effectiveness.